

**Remarks/Arguments:**

With the present response, claims 1, 3-8, 10, 11, 17, 30-33, 47, and 51 are under examination. Claims 9, 12-16, 18-29, 48, and 50 are withdrawn from examination. Method claims 34-46 and 49 have been previously canceled.

**Claim rejections under 35 U.S.C. §103**

Claims 1, 3-6, 10, 11, 30-33, 47, and 51 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,068,634 to Lorentzen Cornelius et al. ("Cornelius") in view of U.S. Patent No. 5,409,495 to Osborn ("Osborn").

Amended claim 1, as amended, recites, *inter alia*, an introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration. The introducer comprises a shaft having a distal tip, an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in the compressed configuration. The introducer further includes anchoring means in at least one of the retrograde portion or the anterograde portion for *engaging and anchoring* the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen and for minimizing relative axial movement between the *engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*.

Cornelius discloses a stent delivery system in which a stent 20 is released from sleeves 22 and 24 *upon expansion of balloon 14* by pulling out of the sleeves. Cornelius, Col. 4, ll. 65-66. The proximal end of Cornelius' stent 20 only engages the body lumen *after* the entire stent is unsheathed. It is clear that balloon 14 of Cornelius does not *engage and anchor* the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen or minimize relative axial movement between the *engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*, but in fact merely provides the mechanism for releasing the stent 20 from sleeves 22 and 24 and expanding the stent 20.

Further, the Office Action further alleges that the balloon of Cornelius, if slightly expanded before the tip was moved distally to release the distal end of the stent could anchor

the proximal end of the stent against axial movement. Office Action, p. 2, last line - page 3, line 1. For several reasons, Applicants respectfully traverse this interpretation of Cornelius. First, the Office Action fails to state where such feature is disclosed in Cornelius. The above Office Action allegation, therefore, merely amounts to an inherency argument. Applicant respectfully submits that Cornelius provides no disclosure of the ability to *distally* move the tip to release the distal end of the stent. To the contrary, distal sleeve 24 is attached along catheter 10 to distal end 27 of balloon 14 by means of an adhesive. The distal end also includes a tapered end 28 that may also be formed of the same adhesive. Cornelius, Col. 4, ll. 37-44 and FIG. 1. Applicants respectfully submit that the tip of Cornelius *cannot* be moved distally to release the distal end of the stent, as is improperly alleged in the Office Action.

Second, according to Cornelius, the expansion of balloon 14 unsheaths stent 20 from sleeves 22, 24. Cornelius, Col. 4, ll. 65-66. Cornelius provides no disclosure of being able to *engage and anchor* the proximal end of stent 20 after expansion of the proximal end into the expanded configuration in the body lumen *or minimize relative axial movement between the engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*, as is recited in amended claim 1.

The Office Action further alleges that, although the distal tip of Cornelius is mounted to the catheter with an adhesive, it is still capable of being removed. Office Action, page 6, ll. 10-11. First, Applicants disagree with this analysis of Cornelius. The distal tip is not mounted to the catheter *with* an adhesive; the distal tip *is* an adhesive. Cornelius, Col. 4, ll. 42-44. Second, the fact that Cornelius discloses that the distal tip is an adhesive leads one to understand the importance of the adhesive nature of the tip relative to the catheter, and that the distal tip is not to be removed from the catheter.

The Office Action further alleges that the balloon is used to set the stent against the vessel wall when inflated to a high enough pressure, and that this would anchor the proximal end of the stent against the vessel wall after expansion of that proximal end. Office Action, page 6, ll. 12-14. The Office Action further alleges that once the stent is placed against the vessel wall via the balloon, the balloon minimizes axial movement of the stent and that, while the balloon is expanded to this high pressure, the remaining distal portion of the stent is also unsheathed. Office Action, page 6, ll. 14-17.

Applicants respectfully submit that this interpretation of Cornelius is flawed. The Office Action is presuming that the device disclosed by Cornelius can independently expand the proximal end of the stent, and then separately and secondly expand the distal end of the stent.

Cornelius does not disclose that the proximal end of the stent can be inflated prior to and/or separately from the distal end of the stent. As discussed above, Cornelius discloses that "[s]tent 20 is released from sleeves 22 and 24 upon expansion of balloon 14 by pulling out of the sleeves and the bunching back of the sleeves." Col. 4, ll. 65-67. Cornelius provides no disclosure of being able to engage and anchor the proximal end of stent 20 such that *after expansion of the proximal end* into the expanded configuration in the body lumen it can then minimize relative axial movement between the *engaged, anchored, expanded proximal end* and the body lumen *during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*, as is recited in amended claim 1.

Similar to Cornelius, Osborn fails to disclose or suggest the claimed feature of anchoring means for engaging and anchoring the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration.

Because both Cornelius and Osborn fail to disclose the feature of anchoring means for engaging and anchoring the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration and for minimizing relative axial movement between the engaged, anchored, expanded proximal end and the body lumen *during unsheathing of a remaining portion of the endoluminal device*, Applicants respectfully submit that the rejection of claim 1, as amended, fails to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 1.

Claims 3-6, 10, 11, and 30-33 all ultimately depend from claim 1 and Applicants respectfully submit that these claims are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 1. Applicants respectfully request reconsideration and allowance of claims 3-6, 10, 11, and 30-33.

#### **Rejection of independent claim 47**

Amended claim 47 recites, *inter alia*, an introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration. The introducer comprises a retrograde portion and an antegrade portion comprising a distal tip and an antegrade sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the antegrade portion of the introducer. A shaft is attached to the distal tip and extending concentrically through a central lumen defined by the antegrade portion and retrograde portion. An inner sheath is mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in the

compressed configuration. An endoluminal device is mounted concentrically over the shaft in the central lumen and has a distal portion contained by the antegrade portion and a proximal end contained by the retrograde portion. An inflatable balloon is mounted radially inside only the retrograde portion and sized to *engage and anchor* the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the *engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion*.

Similar to claim 1, both Cornelius and Osborn fail to disclose or suggest the claimed feature of an inflatable balloon that engages and anchors the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the *engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion*, as is recited in amended claim 47.

Because both Cornelius and Osborn fail to disclose the feature of an inflatable balloon that engages and anchors the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the *engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion*, as is recited in amended claim 47, Applicants respectfully submit that the rejection of claim 1 fails to establish a *prima facie* case of obviousness. Applicants therefore respectfully request reconsideration and allowance of claim 47.

#### **Rejection of claims 7, 8, and 17**

Claims 7, 8, and 17 stand rejected under 35 U.S.C. §103(a) as unpatentable over Cornelius in view of Osborn and further in view of U.S. Patent No. 6,022,336 to Zadno-Azizi et al. ("Zadno-Azizi"). Claims 7, 8, and 17 ultimately depend from claim 1.

Zadno-Azizi is cited for allegedly disclosing the use of a reinforcing layer to provide increased stiffness and for providing variable stiffness along the length of an introducer. Zadno-Azizi fails to make up for the deficiencies discussed above with respect to claim 1. Applicants therefore respectfully submit that claims 7, 8, and 17 are allowable over the proposed combination of Cornelius, Osborn, and Zadno-Azizi for at least the same reasons set forth above with respect to claim 1. Applicants respectfully request reconsideration and allowance of claims 7, 8, and 17.

**Withdrawn claims**

Claims 9, 12-16, 18-29, 48, and 50 are presently withdrawn. For withdrawn claims dependent upon claims deemed to be allowed in the next Office Action, Applicants respectfully request reintroduction and allowance of these claims.

**Conclusion**

In light of the above arguments, Applicants respectfully submit that the present application is in condition for allowance. Prompt reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,



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